

MAY 23 2006

K061072

**MAQUET**

**510 (K) Summary [as required by 21 CFR 807.92(c)]**

Submitter: Maquet Cardiopulmonary AG  
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Germany

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Date Prepared: April 07, 2006

Device Trade Name: RotaFlow Centrifugal Pump with Safeline Coating

Common/Usual Name: Centrifugal pump, coated

Classification Names: Pump, blood, non-roller-type, cardiopulmonary;  
(21 CFR 870.4360, product code: KFM)

Predicate Devices: RotaFlow Centrifugal Pump (K991864)  
Quadrox Hollow Fiber Membrane Oxygenator  
Safeline (K992559, K030264)

**Device Description**

The Jostra RotaFlow Centrifugal Pump with Safeline Coating is a sterile, non-pyrogenic device for single use only and is not to be re-sterilized by the user.

The RotaFlow Centrifugal Pump with Safeline Coating is indicated as a component of the extracorporeal circuit and is intended to be used exclusively in conjunction with the RotaFlow-Console, the RotaFlow Drive Unit and the RotaFlow Emergency Drive. The device is not designed or intended for use except as indicated. The centrifugal pump is indicated for single use as a pump for up to 6 hrs.

The RotaFlow is a blood pump that functions on the basis of the centrifugal principle, whereas the drive is based on a magnetic system. A sapphire ball and a PE calotte guarantee low friction bearing.

The centrifugal pump has a spinning rotor with flow channels which impart rotary motion to the incoming blood, directing it through a spiral housing to the outflow port. The Rotor is shrouded. It forms the flow channels with 4 fan-shaped members. The flow is guided from the centre of the pump to the periphery of the pump, where it is then forced into the flow channel by means of a spiral flow channel the cross-section of which increases in the direction of flow. The RotaFlow Centrifugal Pump allows for pulsatile and non-pulsatile flow.

The RotaFlow Centrifugal Pump comes with an integrated flow probe connector.

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The design principle minimizes blood traumatization and stress with optimum flow guidance. Additionally, the pump design results in no stagnant blood zones and a small priming volume of 32 ml which allows for minimal mean transit time (MTT).

## **Statement of Indications for Use:**

The Jostra RotaFlow Centrifugal Pump with Safeline Coating as well as the Jostra RotaFlow Centrifugal Pump are indicated as a component of the extracorporeal circuit for pumping liquid matter e.g. blood and can be used in conjunction with the Jostra RotaFlow Console. The utilization period of this device is restricted to 6 hours. The device is not designed or intended for use except as indicated.

## **Statement of Technical Characteristics Comparison**

The two devices differ in that the blood contacting surfaces of the Jostra RotaFlow Centrifugal Pump with Safeline Coating has been treated with the Safeline Coating. Otherwise, indications for use, materials, components, design, performance characteristics and sterilization for the two devices are the same. The safety of the Safeline Coating has been shown with the Quadrox Safeline Oxygenator (K992559). Due to equivalence of indications for use, materials, design and functional characteristics, the device raises no new safety or effectiveness issues.

## **Determination of Substantial Equivalence**

Evaluation and testing on safety and effectiveness was executed to demonstrate that the Jostra RotaFlow Centrifugal Pump with Safeline Coating described in this submission is substantially equivalent to the Jostra RotaFlow Centrifugal Pump as a pump and to the Quadrox Safeline Hollow Fiber Membrane Oxygenator regarding the Safeline coating.

The following areas have been tested and / or evaluated:

- Integrity of the RotaFlow
- Performance of the RotaFlow
- Stability of the Coating
- Biocompatibility
- Sterility

## **Conclusion**

The data given demonstrate that the Jostra RotaFlow Centrifugal Pump with Safeline Coating is substantially equivalent to the named predicate devices which hold currently market clearance.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 23 2006

Maquet Cardiopulmonary AG  
c/o Ms. Katrin Schwenkglens  
Hechinger Strasse 38  
Hirrlingen, Germany 72145

Re: K061072  
Jostra RotaFlow Centrifugal Pump with Safeline Coating  
Regulation Number: 21 CFR 870.4360  
Regulation Name: Pump, blood, non-roller-type, cardiopulmonary  
Regulatory Class: Class III (three)  
Product Code: KFM  
Dated: April 7, 2006  
Received: April 17, 2006

Dear Ms. Schwenkglens

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Jostra RotaFlow Centrifugal Pump with Safeline Coating \_\_\_\_\_

Indications for Use:

The Jostra RotaFlow Centrifugal Pump with Safeline Coating is indicated as a component of the extracorporeal circuit for pumping liquid matter e.g. blood and can be used in conjunction with the Jostra RotaFlow Console. The utilization period of this device is restricted to 6 hours. The device is not designed or intended for use except as indicated.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Cardiovascular Devices

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(Posted November 13, 2003)